K11 1702

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MAR 22 2012

510(K) SUMMARY

Date Prepared:

June 16, 2011

Owner and Contact Person:

Owner/Operator	Owner/Operator #: 9098803 Fenwal, Inc. Three Corporate Drive Lake Zurich, IL 60047
Contact Name: Title: Address: Telephone: Fax: E-mail:	Kim Forch Manager, Regulatory Affairs Three Corporate Drive Lake Zurich, IL 60047 847-550-7962 847-550-2960 kim.forch@fenwalinc.com

Device Name(s):

AMICUS Separator System

Common Name:

Automated Blood Cell Separator (Centrifugal Separation Principle)
Automated Separator, Blood Cell and Plasma, Therapeutic*

Classification Name:

21 CFR 864.9245 Automated Blood Cell Separator: Class II
Automated separators, used for separation of blood cells and plasma for therapeutic purposes, have not been classified under a regulation by the Center for Devices and Radiological Health due to pre-amendment status.*

Classification Panel:

GKT (Hematology panel)- Separator, Automated, Apheresis
LKN (Gastroenterology/Urology panel) – Unclassified*

*Subject of this 510(k) application

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:

Fenwal, Inc. is claiming substantial equivalence of the AMICUS Separator System when used for Therapeutic Plasma Exchange (TPE) with the currently marketed AMICUS Separator System, indicated for the collection of blood components and mononuclear cells, which was most recently cleared to market under 510(k) BK090065 on March 4, 2010. This includes all operating protocols and changes previously cleared for the AMICUS Separator System. Depending on the AMICUS Separator System apheresis kit used in the collection of products, the AMICUS Separator System has been cleared to collect:

- Platelet Pheresis, Leukocytes Reduced (single, double, or triple units)
- Platelet Pheresis, Leukocytes Reduced, Platelet Additive Solution (InterSol) (single, double or triple units)
- Plasma
- Fresh Frozen Plasma
- Source Plasma
- Red Blood Cells, Leukocytes Reduced (by apheresis)
- Mononuclear Cells

Fenwal, Inc. is also claiming substantial equivalence of the AMICUS Separator System for use in Therapeutic Plasma Exchange to the Caridian BCT COBE Spectra Apheresis System Therapeutic Plasma Exchange procedure which was cleared to market under K900105 on March 22, 1991.

Device Description:

The AMICUS separator is a continuous-flow, centrifugal device that separates whole blood into its components. Blood components are collected using sterile fluid path, single-use, apheresis kits. The cells are centrifugally separated within the kit by density differences.

The Therapeutic Plasma Exchange (TPE) procedure is an apheresis collection procedure coupled with an infusion procedure. The collected plasma, which contains most of the anticoagulant, is pumped to a waste container(s). The patient's WBCs, RBCs, the majority of platelets and a small amount of plasma and anticoagulant are mixed with a physician-prescribed replacement fluid, such as FFP, human albumin and/or crystalloid solutions, and returned to the patient. This process continues until the target plasma volume has been removed and replaced per physician order.

The operator is responsible for preparing and monitoring the patient as well as operating and monitoring the AMICUS separator during the TPE procedure. The operator controls the separator through a touch screen. When necessary, the operator is alerted to problems, or given notes via messages displayed on the screen with corresponding audible alarms. Once complete, the operator disconnects the donor/patient, removes the kit, and disposes of the kit per institutional SOPs. The kit is packaged in a recyclable plastic tray.

Statement of Intended Use:

In addition to the currently-cleared intended uses for the AMICUS Separator System, this application supports the expansion of the intended use as follows:

The AMICUS Separator System is an automated blood cell separator indicated to perform Therapeutic Plasma Exchange (TPE).

Technological Characteristics as compared to the Predicate Device:

The technological characteristics of the AMICUS separator remain the same as the currently marketed AMICUS device, and are substantially equivalent to the COBE Spectra device. This includes the centrifuge system, fluid control system, safety management system (including safety sensors and alarms), and anticoagulant management system which determines the anticoagulation level in the system and the rate at which citrate can be returned to the patient. The physical design of the AMICUS separator instrument is identical to the predicate AMICUS device. The design includes three main areas of operation (touch screen, top panel and centrifuge) that are substantially equivalent to those on the predicate COBE Spectra device.

The disposable device design requirements for the AMICUS TPE kit are similar to those for the currently marketed AMICUS MNC kit and COBE Spectra TPE kit. The kit is designed to be a single use, sterile fluid path set that is used with anticoagulant and saline solutions, as well as plasma replacement fluids. Like the currently marketed AMICUS disposables, the TPE kit is made of PVC and non-PVC plastics, and is manufactured using the same validated methods. The TPE kit is terminally sterilized by irradiation using the same sterilization methods and procedures as the cleared AMICUS disposables kits.

The functions of the AMICUS TPE procedure are substantially equivalent to the COBE Spectra TPE procedure in its plasma collection efficiency while accurately achieving a patient's target end fluid balance.

Performance Data:

System validation and verification activities and clinical testing have been performed on the AMICUS Separator System for performance of TPE procedures. Software changes were verified and validated as part of a total system testing effort. System validation and verification testing activities were conducted to demonstrate that the instrument, software and disposable operate together per specification and intended use.

Clinical evaluation of the AMICUS Separator System for performance of TPE showed that the AMICUS separator can be used to safely and effectively perform TPE procedures in patients. The primary study objective was achieved by demonstrating that the efficiency of plasma removal in the AMICUS separator (Test group) was statistically non-inferior to the efficiency of plasma removal in the Control group at a margin of 15%. In addition, the efficiency of plasma removal in the Test group was statistically superior

to the efficiency of plasma removal in the Control group. The mean efficiency of plasma removal for the test procedures was 81.9% with a range of 68% to 96% compared to 75.2% with a range of 61% to 88% for the control procedures.

The higher efficiency of plasma removal for the test device resulted in less plasma processed and subsequently less ACD returned to the patient on average in the test procedures than in the control procedures while accurately maintaining fluid balance. The assessment of platelet loss in the waste plasma demonstrated only low levels of platelets that were within the range of the control device. The plasma hemoglobin in the waste plasma was also low for the AMICUS device and similar to that of the control procedures.

Conclusion:

The AMICUS Separator System when used for Therapeutic Plasma Exchange is substantially equivalent to the current AMICUS Separator System and the Caridian BCT COBE Spectra Apheresis System Therapeutic Plasma Exchange procedure. The AMICUS Separator System has substantially equivalent plasma collection efficiency to the Spectra Apheresis System when used for TPE while accurately achieving expected fluid balance for the patient. The AMICUS TPE kits are comparable to the current AMICUS apheresis kits in quality, design, method of manufacture and sterilization.

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510(K) SUMMARY

Date Prepared:

June 16, 2011

Owner and Contact Person:

Owner/Operator	Owner/Operator #: 9098803 Fenwal, Inc. Three Corporate Drive Lake Zurich, IL 60047
Contact Name: Title: Address: Telephone: Fax: E-mail:	Kim Forch Manager, Regulatory Affairs Three Corporate Drive Lake Zurich, IL 60047 847-550-7962 847-550-2960 kim.forch@fenwalinc.com

Device Name(s):

Blood Component Filter Set with Vented Spike and Luer Adapter

Common Name:

Set, Blood Transfusion

Classification Name:

21 CFR 880.5440 Intravascular Administration Set: Class II, Blood Transfusion sets have been classified by the General Medical Device Panel as Intravascular administration set for General Hospital and Personal Use.

Classification Panel:

BRZ (General Hospital and Personal Use Therapeutic Devices)

Legally Marketed Device Under Which Substantial Equivalence is Being Claimed:

Fenwal, Inc. is claiming substantial equivalence of the Blood Component Filter Set with Vented Spike and Luer Adapter to the Fenwal Blood Component Recipient Set with Standard Blood Filter and Luer Adapter (Fenwal product code 4C2160) which was cleared to market under K073339 on March 3, 2008.

Device Description:

The Blood Component Filter Set with Vented Spike and Luer Adapter is an optional accessory intended to be used in conjunction with the AMICUS Separator System in Therapeutic Plasma Exchange (TPE) procedures to administer physician prescribed replacement fluids during the TPE procedure, when blood component filtration is needed (e.g. when using fresh frozen plasma). The filter set has a common blood transfusion set design and is comprised of a blood component filter, tubing, vented spike and a luer lock/cap. The filter set is a single use, sterile fluid path intravascular administration set. The filter set is connected to the TPE kit via the male luer connector and the vented spike is used to access the prescribed replacement fluid container. The flow rate through the filter set is controlled by the AMICUS Separator System.

Statement of Intended Use:

The Blood Component Filter Set with Vented Spike and Luer Adapter is indicated for the administration of blood and blood components during a therapeutic plasma exchange procedure. For use with the AMICUS Separator System.

Technological Characteristics as compared to the Predicate Device:

The Blood Component Filter Set with Vented Spike and Luer Adapter to be used with the AMICUS Separator System is technologically equivalent to the currently marketed Fenwal Blood Component Recipient Set with Standard Blood Filter and Luer Adapter. The design of the new filter set is based on the currently marketed device. It uses the same tubing and filter assembly used in the currently marketed device. It uses a new vented spike assembly that would allow it to be used with rigid containers as well as the flexible containers. The male luer adapter allows for connection to the AMICUS TPE kit.

The disposable device design requirements for the Blood Component Filter Set are similar to those for the predicate device. The new filter set is designed to be a single use, sterile fluid path set that is used for the administration of blood and blood components. Like the predicate, the new filter set is made of PVC and other thermoplastics, and is manufactured using the same validated processes. The filter set is sterilized by irradiation using the same sterilization methods and procedure as the predicate device.

Performance Data:

Performance testing of the Blood Component Filter Set consisted of verification and validation that the device functions per specification and as intended for use with the AMICUS TPE kit. The filter set was tested in conjunction with the AMICUS Separator System TPE kit performance (system validation and verification activities, and bench testing). These testing activities demonstrate that the Blood Component Filter Set, when used with the AMICUS Separator System with the TPE kit, performs as intended in a safe and effective manner.

Conclusion:

The Blood Component Filter Set with Vented Spike and Luer Adapter when used in conjunction with the AMICUS Separator System for therapeutic plasma exchange is substantially equivalent to the Blood Component Recipient Set with Standard Blood Filter and Luer Adapter (Fenwal product code 4C2160).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Kim Forch
Manager, Global Regulatory Affairs
Fenwal, Inc.
Three Corporate Drive
LAKE ZURICH IL 60047

MAR 22 2012

Re: K111702
Trade/Device Name: AMICUS Separator System – Use in Therapeutic Plasma Exchange
Blood Component Filter Set with Vented Spike and Luer Adapter
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKN
Dated: March 16, 2012
Received: March 20, 2012

Dear Ms. Forch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111702

Not yet assigned

Device Name:

AMICUS Separator System

Indication(s) for Use:

The AMICUS Separator System is an automated blood cell separator indicated for the collection of blood components and mononuclear cells.

The AMICUS Separator System is an automated blood cell separator indicated to perform Therapeutic Plasma Exchange (TPE).

Prescription Use: X	AND/OR	Over-the-counter Use:
21 CFR 801 Subpart D		21 CFR 801 Subpart C

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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111702

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K111702

Not yet assigned

Device Name:

Blood Component Filter Set with Vented Spike and Luer Adapter

Indication(s) for Use:

The Blood Component Filter Set with Vented Spike and Luer Adapter is indicated for the administration of blood and blood components during a therapeutic plasma exchange procedure. For use with the AMICUS Separator System.

Prescription Use: **X**	AND/OR	Over-the-counter Use:
21 CFR 801 Subpart D		21 CFR 801 Subpart C

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111702